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2009 JAN -7 A 8:14

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Application No. : **2,459,603**
Owner : MEDTRONIC, INC.
Title : **ELECTRICAL TISSUE STIMULATION APPARATUS AND METHOD**
Classification : A61N 1/05 (2006.01)
Your File No. : **66742-848 (JMc:bba)**
Examiner : Patrick Abou-Antoun

YOU ARE HEREBY NOTIFIED OF A REQUISITION BY THE EXAMINER IN ACCORDANCE WITH SUBSECTION 30(2) OF THE *PATENT RULES*. IN ORDER TO AVOID ABANDONMENT UNDER PARAGRAPH 73(1)(A) OF THE *PATENT ACT*, A WRITTEN REPLY MUST BE RECEIVED WITHIN 6 MONTHS AFTER THE ABOVE DATE.

This application has been examined taking into account the:

Description, pages 1-21, as originally filed;
Claims, 1-47, as received on April 22, 2003 during the international phase; and
Drawings, pages 1-14, as originally filed.

This application has been examined taking into account applicant's correspondence on prior art received in this office on December 12, 2006.

The number of claims in this application is 47.

The search of the prior art has revealed the following:

References Applied

Canadian Patent Application

D1: CA 2361777 May 10, 2002 A61N 1/04 Maltese

United States Patent

D2: US 5,259,394 November 9, 1993 A61N 1/05 Bens

D1 discloses an implantable electrode needle having an elongate lead body an extendable distal portion capable of axial movement between retracted and extended positions. In the retracted position, the extendable portion is in a rectilinear shape and constrained within the lead body; in the extended position, the extendable portion is deployed and curls upon itself.

D2 discloses an electrode needle comprising a hollow guide needle and a RF active filament threaded into the needle. The filament is configured to pass from a deformed rectilinear shape when the filament is in a retracted position, to an undeformed spiral shape when the filament is in an active forward position

The examiner has identified the following defects in the application:

Novelty

Claim 1 does not comply with paragraph 28.2(1)(d) of the *Patent Act*. The subject matter defined in this claim was disclosed in co-pending application D1, which claims a priority date prior to the claim date of the present application.

Independent claim 1 is directed to an implantable lead for stimulating nerve tissue, muscle or organs, comprising:

- an elongate body; and
- at least one extendable member having a proximal portion and a distal portion adapted to curl upon itself when not constrained and capable of axial movement between a retracted position and an extended position.

When in the retracted position, the distal and proximal portions are constrained within the lead body, and when in the extended position the distal portion is deployed out of the lead body and tightly curls upon itself.

The aforementioned characteristic features are taught in the reference document D1 and therefore cannot be considered novel.

Document D1 discloses an implantable lead for stimulating nerve tissue, muscle or organs, comprising:

- an elongate body (11); and
- at least one extendable member having a proximal portion (12) and a distal portion (13) adapted to curl upon itself when not constrained and capable of axial movement between a retracted position and an extended position.

In the retracted position, the distal (13) and proximal (21) portions are constrained within the lead body (11), and when in the extended position the distal portion is deployed out of the lead body and tightly curls upon itself (page 2, lines 9-15).

As such, claim 1 fails to recite any additional features or characteristics that would patentably distinguish it from the apparatus disclosed in D1.

Obviousness

Claim 1 does not comply with section 28.3 of the *Patent Act*. The subject matter of this claim would have been obvious on the claim date to a person skilled in the art or science to which it pertains having regard to D2.

Reference document D2 teaches an implantable electrode needle suitable for stimulating nerve tissue, muscle or organs. Referring to figure 2, the electrode needle comprises:

- an elongate lead body (1);
- an extendable member (7) capable of axial movement between retracted and deployed positions, further comprising a distal portion (6) shaped to pass from a rectilinear shape when the extendable member is in a retracted position, to a spiral shape when the extendable member is in an extended position (column 2, lines 44-52).

Therefore, claim 1 fails to recite any additional features or characteristics that would patentably distinguish it from the cited reference D2. The wording in this claim reads on the teachings of D2, and further restriction is required in order to define a patentable advance.

Claims 2-27 do not comply with section 28.3 of the *Patent Act*. The subject matter of these claims would have been obvious on the claim date to a person skilled in the art or science to which they pertain having regard to D2.

Dependent claims 2-27 do not contain any additional features which, in combination with the features of the claims to which they refer, patentably distinguish them over the description of D2. The elements recited represent either features that are already known from the prior art, or common implementation and design details which are well known to a person skilled in the art. Therefore, claims 2-27 are objected to for the same reasons as the claims to which they refer.

Miscellaneous

Section 80(1)(a) of the *Patent Rules* requires that the title of the invention be short and precise. As the claimed invention does not include any methods, a more suitable title would be "Electrical Tissue Stimulation Apparatus".

Also, a new set of claims should be submitted wherein cancelled claims 29-47 have been removed.

In view of the foregoing defects, the applicant is requisitioned, under subsection 30(2) of the *Patent Rules*, to amend the application in order to comply with the *Patent Act* and the *Patent Rules* or to provide arguments as to why the application does comply.

Patrick Abou-Antoun
Patent Examiner
819-994-7470